

Washington, D.C. – U.S. Reps. Tom Rooney (FL-16) and Diana DeGette (CO-01) today will introduce the [“Preserving Access to Life-Saving Medications Act,”](#) a bipartisan bill to improve patient safety by reducing shortages of life-saving drugs.

“Across the country, hospitals and physicians are facing critical shortages of common, life-saving drugs, like anesthetics, pain medications and cancer therapies,” Rooney said. “No patient should suffer because of a drug shortage that could have been prevented.

“The earlier doctors, suppliers and the FDA are able to communicate a potential drug shortage, the better equipped they are to respond and possibly prevent a disruption from occurring. Because our goal is to increase access to needed drugs, we have worked carefully to ensure that the bill’s reporting requirements will not put undue burdens – which might increase costs for hospitals and patients – on manufacturers.”

“This bill represents an important first step towards addressing prescription drug shortages, which are far more rampant across the country than many realize,” said DeGette. “Every year there are approximately 200 critical shortages of life-saving drugs in America, ranging from anesthesia to cancer-fighting medicines for children, and in many cases, there are no safe alternatives. Sadly, this problem is only worsening, but the early warning system this bill creates represents an immediate safeguard to help prevent sudden shortages of these life-saving medications.”

According to the Food and Drug Administration (FDA), drug shortages have nearly tripled since 2005 and hit a record high of 178 last year, forcing doctors to delay or alter patient care plans. In many instances, no safe alternatives to these drugs exist, leaving patients with an increased risk of side effects and adverse drug interactions.

Currently, only sole-source manufacturers of medically necessary drugs are required to report discontinuances to the FDA, so the agency can help mitigate the disruption and notify doctors. In fact, the FDA says 38 shortages were prevented in 2010 from companies who provided early notification of a possible disruption. The DeGette-Rooney bill would expand that law to combat drug shortages by:

- Requiring manufacturers of all prescription drugs, including biologics, to notify the FDA of any discontinuance or interruption in the production of a drug at least six months in advance;
- In the event of an unplanned discontinuance or interruption, requiring manufacturers to notify the FDA as soon as possible;
- Instructing the Secretary to publish these notifications and any actual drug shortage on its website, and work to distribute this information to appropriate health care providers and patient organizations; and,
- Directing a GAO study to examine the possible causes of drug shortages, including manufacturing problems, breakdown in supply chains and delivery systems, and restrictive regulatory requirements.

The American Hospital Association, American Society of Clinical Oncology, American Society of Health-System Pharmacists, and Institute for Safe Medication Practices have endorsed the bill, as has the generic drug manufacturer Hospira, Inc.

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